

For Immediate Release

March 30, 2017 Contact: Mark S. Birenbaum, Ph.D., NILA Administrator, (314) 241-1445

CMS Temporarily Delays the Medicare Laboratory Payment Reform Rule

WASHINGTON, DC – The National Independent Laboratory Association (NILA) welcomed the <u>announcement</u> by the Centers for Medicare and Medicaid Services (CMS) that it will allow laboratories more time – until May 30, 2017 – to report laboratory payment data as part of a regulation to alter Medicare payments for clinical laboratory testing. The data reporting period for PAMA had been scheduled to conclude on Friday, March 31, 2017.

Last week, 10 national organizations representing stakeholders across the clinical laboratory community, including the National Independent Laboratory Association (NILA) asked Health and Human Services Secretary Tom Price, MD to delay and make needed changes to the Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule, which implemented Section 216 of the *Protecting Access to Medicare Act of 2014* (PAMA). [Letter to Secretary Price]

"NILA is pleased that CMS and HHS officials recognize the significant challenge that community laboratories are facing when trying to comply with the PAMA regulation," says Mark Birenbaum, Ph.D., NILA Administrator. "We remain committed to ensuring that the conversation continues during this time window and that CMS and Congress seriously work with stakeholders to address the major flaws with the regulation to determine the best solution to laboratory payment reform."

In their letter to HHS Secretary Price, stakeholders reiterated concerns that had been expressed in 2016 by the HHS Office of the Inspector General that the regulation may lead to inaccurate Medicare payment rates for lab tests. The stakeholders are requesting that CMS delay the implementation of laboratory payment reforms under PAMA for one year in order to resolve data collection and reporting errors and restrictions that prohibit the government from assessing data from all segments of the laboratory market.

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"Beyond operational data issues, the significant regulatory definition for "applicable laboratory" must be reassessed and redefined before CMS moves forward and resets laboratory payment rates. PAMA payment reforms depend on an accurate measurement of true market rates; however, the Health and Human Services (HHS) Office of Inspector General (OIG) analysis of the current CMS definition for "applicable laboratory" assessed that only 5 percent of clinical laboratories will report data, with an estimated complete exclusion of hospital laboratories."

"This Administration has an opportunity to seriously reflect on the concerns raised by NILA and the broad laboratory stakeholder community. To ensure affordability and access to laboratory testing within Medicare and across our health care system, we must preserve a competitive laboratory market and maintain a strong community-based workforce. NILA stands willing to work in collaboration with Secretary Price and CMS Administrator Seema Verma to address our concerns during this reporting extension and protect access to the clinical laboratory testing relied on by physicians and patients for medical diagnoses, treatment, and care management."

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The National Independent Laboratory Association (NILA) is made up of members who are small community and multi-state regional independent clinical laboratories working with physician practices, hospitals, outpatient care settings, skilled nursing facilities, and home health patients to provide essential clinical laboratory services to Medicare beneficiaries, particularly those in underserved communities and hard-to-reach care settings. Every day, NILA members provide diagnostic laboratory services and results, upon which physicians base their clinical decisions for the Medicare beneficiaries they serve.